### § 808.98 West Virginia.

(a) The following West Virginia medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption: West Virginia Code, sections 30–26–14 (b) and (c) and section 30–26–15(a) on the condition that in enforcing section 30–26–15(a) West Virginia apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter.

(b) The following West Virginia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: West Virginia Code, section 30–26–14(a).

[45 FR 67337, Oct. 10, 1980, as amended at 53 FR 35314, Sept. 13, 1988]

### § 808.101 District of Columbia.

(a) The following District of Columbia medical device requirements are enforceable, notwithstanding section 521 of the act, because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Act 2–79, section 5, to the extent that it requires an audiological evaluation for children under the age of 18.

(2) Act 2–79, section 6, on the condition that in enforcing section 6(a)(5), the District of Columbia apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Act 2–79, section 5, except as provided in paragraph (a) of this section.

[46 FR 59236, Dec. 4, 1981]

# PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

## Subpart A—General Provisions

Sec.



## Subpart B—Labeling



## Subpart C—Requirements for Manufacturers and Producers



AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

## Subpart A—General Provisions

### § 809.3 Definitions.

(a) *In vitro diagnostic products* are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.

(b) A *product class* is all those products intended for use for a particular determination or for a related group of determinations or products with common or related characteristics or those intended for common or related uses. A class may be further divided into subclasses when appropriate.

(c) [Reserved]

(d) *Act* means the Federal Food, Drug, and Cosmetic Act.

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 7484, Feb. 1, 1980]

### § 809.4 Confidentiality of submitted information.

Data and information submitted under § 809.10(c) that are shown to fall within the exemption established in § 20.61 of this chapter shall be treated as confidential by the Food and Drug Administration and any person to

whom the data and information are referred. The Food and Drug Administration will determine whether information submitted will be treated as confidential in accordance with the provisions of part 20 of this chapter.

[45 FR 7484, Feb. 1, 1980]

## Subpart B—Labeling

### § 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class or as provided in paragraph (e) of this section. Section 201(k) of the act provides that ''a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.''

(1) The proprietary name and established name (common or usual name), if any.

(2) The intended use or uses of the product.

(3) For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from biological material, the source and a measure of its activity. The quantity, proportion, concentration, or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc.

(4) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement ''For In Vitro Diagnostic Use'' and any other limiting statements appropriate to the intended use of the product.

(5) For a reagent, appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the original container. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.166 of this chapter.

(6) For a reagent, a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following:

(i) An expiration date based upon the stated storage instructions.

(ii) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, beyond its appropriate standards.

(iii) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards.

(7) For a reagent, a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate. If more than a single determination may be performed using the product, any statement of the number of tests shall be consistent with instructions for use and amount of material provided.

(8) Name and place of business of manufacturer, packer, or distributor.

(9) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(i) If it is a multiple unit product, the lot or control number shall permit tracing the identity of the individual units.